

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6003. Class E Airspace Designated as an Extension to a Class C Surface Area.

* * * * *

AEA NJ E3 Atlantic City, NJ [Amended]

Atlantic City International Airport, NJ
(Lat. 39°27'27" N., long. 74°34'38" W.)
Atlantic City VORTAC

(Lat. 39°27'21" N., long. 74°34'35" W.)

That airspace extending upward from the surface within 2.7 miles either side of the Atlantic City VORTAC 303° radial extending from the 5-mile radius to 7.4 miles northwest of Atlantic City International Airport.

Paragraph 6005. Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

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AEA NJ E5 Atlantic City, NJ [Amended]

Atlantic City International Airport, NJ
(Lat. 39°27'27" N., long. 74°34'38" W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Atlantic City International Airport.

Issued in College Park, Georgia, on December 29, 2016.

Debra L. Hogan,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017-00302 Filed 1-13-17; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection**DEPARTMENT OF THE TREASURY****19 CFR Part 133**

[USCBP-2016-0076]

RIN 1515-AE21

Donations of Technology and Support Services To Enforce Intellectual Property Rights

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes amendments to the U.S. Customs and Border Protection (CBP) regulations pertaining to the enforcement of

intellectual property rights. Specifically, CBP is proposing amendments to implement a section of the Trade Facilitation and Trade Enforcement Act of 2015 which requires CBP to prescribe regulatory procedures for the donation of technologies, training, or other support services for the purpose of assisting CBP in intellectual property enforcement. The proposed regulations would enhance CBP's intellectual property rights enforcement capabilities. **DATES:** Comments must be received on or before March 3, 2017.

ADDRESSES: You may submit comments, identified by *docket number*, by one of the following methods:

- Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the instructions for submitting comments via Docket No. USCBP-2016-0076.

- *Mail:* Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229-1177.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Submitted comments may be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of Trade, Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229-1177. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

FOR FURTHER INFORMATION CONTACT: Garrett D. Wright, Chief, Donations Acceptance Program, Office of Field Operations, U.S. Customs and Border Protection, telephone (202) 344-2344.

SUPPLEMENTARY INFORMATION:**Public Participation**

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. U.S. Customs and Border

Protection (CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rulemaking. Comments that will provide the most assistance to CBP will reference a specific portion of the proposed rulemaking, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change. See **ADDRESSES** above for information on how to submit comments.

Background

The Trade Facilitation and Trade Enforcement Act of 2015 (TFTEA), Public Law 114-125, 130 Stat. 122 (19 U.S.C. 4301 note), enacted February 24, 2016, includes an assortment of trade facilitation and trade enforcement provisions, including several that focus on improving CBP's intellectual property rights (IPR) enforcement at the border. Section 308(d) of the TFTEA requires the Commissioner of CBP to prescribe regulations that will enable CBP to receive donations of technologies, training, and other support services for the purpose of assisting CBP in detecting and identifying imports that infringe intellectual property rights.

In House Report 114-114, the House Ways and Means Committee stated that CBP should take steps to ensure that personnel dedicated to enforcement of IPR are effectively trained to detect and identify infringing imports. The Committee noted that much of the expertise in this area lies within the private sector, and that companies are most knowledgeable about their products and can provide valuable training to CBP on detection. H.R. 114-114 at 76.

Discussion of Proposed Amendments

New Subpart H to Part 133—Donations of Intellectual Property Rights Technology and Support Services

§ 133.61

This document proposes to implement section 308(d) of the TFTEA by promulgating a new subpart H to part 133 of title 19 of the Code of Federal Regulations, entitled "[D]onations of Intellectual Property Rights Technology and Support Services," which would provide for the receipt and acceptance by CBP of donations of hardware, software, equipment, and similar technologies, as well as training and support services, for the purpose of assisting CBP in enforcing IPR. It is also proposed to add and reserve subpart G to part 133.

New subpart H, as set forth in proposed new § 133.61, prescribes the methods by which donations of IPR technology and support services may be made. Specifically, proposed 19 CFR 133.61(a) sets forth the scope of this section and identifies the relevant authority. Proposed 19 CFR 133.61(b) prescribes the conditions applicable to a donation offer and provides that CBP will notify the donor, in writing, if additional information is requested or if CBP has determined that it will not accept the donation. In this regard, it is noted that CBP will take into consideration all aspects of the proposed donation offer, including whether such offer would pose a real or potential conflict between the interests of the donor and the interests of the government. Proposed 19 CFR 133.61(c) provides that if CBP elects to accept a donation offer, CBP will enter into a signed, written agreement with an authorized representative of the donating entity that commemorates all applicable terms and conditions, and that an agreement to accept training and other support services must provide that the services or training are offered without the expectation of payment and that the service provider expressly waives any future claims against the government.

Authority To Accept Donations

As noted above, pursuant to section 308(d) of the TFTEA, CBP is required to prescribe regulatory procedures for donations of hardware, software, equipment, and similar technologies, as well as training and support services, for the purpose of assisting CBP in enforcing IPR.

Acceptance of such donations must also be consistent with either section 482 of the Homeland Security Act of 2002, as amended by section 2 of the Cross-Border Trade Enhancement Act of 2016 (Pub. L. 114–279), or section 507 of the Department of Homeland Security Appropriations Act of 2004 (Pub. L. 108–90).

Section 482 of the Homeland Security Act replaced section 559 of Title V of Division F of the Consolidated Appropriations Act, 2014 (Pub. L. 113–76) and permits CBP, in consultation with the General Services Administration (GSA), to “enter into an agreement with any entity to accept a donation of personal property, money, or nonpersonal services” to be used for certain CBP activities at most ports of entry where CBP performs inspection services. Generally speaking, donations may be used for certain activities of CBP’s Office of Field Operations, including expenses related to “(A)

furniture, equipment, or technology, including the installation or deployment of such items; and (B) the operation and maintenance of such furniture, fixtures, equipment or technology.” Section 482(a)(3). To implement section 482, CBP will build upon its experience in implementing section 559 of Title V of Division F of the Consolidated Appropriations Act, 2014, where CBP and the GSA issued the *Section 559 Donation Acceptance Authority Proposal Evaluation Procedures & Criteria Framework* in October, 2014.¹ Pursuant to Section 482(c)(3), CBP in consultation with GSA will establish criteria for evaluating donation proposals under Section 482 and make such criteria publicly available.

Donations that may not be accepted under section 482 may be considered under section 507 of the DHS Appropriations Act of 2004. Section 507 of the DHS Appropriations Act of 2004 made the DHS Gifts and Donations account (formerly the Federal Emergency Management Agency “Bequests and Gifts” account) “available to the Department of Homeland Security . . . for the Secretary of Homeland Security to accept, hold, administer and utilize gifts and bequests, including property, to facilitate the work of the Department of Homeland Security.” Title V, Public Law 108–90, 117 Stat. 1153–1154. DHS policy on the acceptance of gifts pursuant to section 507 is contained in DHS Directive 112–02 and DHS Instruction 112–02–001. The Secretary of DHS delegated the authority to accept and utilize gifts to the heads of certain DHS components, including the Commissioner of CBP, in DHS Delegation 0006.

Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This

¹ <https://www.cbp.gov/document/guidance/section-559-donation-acceptance-authority-proposal-evaluation-procedures-and>. Section 483 of the Homeland Security Act, as amended by the Cross-Border Trade Enhancement Act, also exempts from section 482 existing agreements entered into pursuant to section 559, as well as proposals already accepted for consideration by CBP.

proposed rule is not a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this regulation.

This rule proposes amendments to the CBP regulations that would prescribe procedures for the voluntary donation of technology, training, and other support services for the purpose of assisting CBP in enforcing IPR, as required by section 308(d) of the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114–125, 130 Stat. 122 (19 U.S.C. 4301 note). These donations would improve CBP’s knowledge of intellectual property and improve its ability to detect infringing articles and prevent their importation.

Because donations under this rule would be voluntary, CBP assumes that entities would only make donations if they believe it is in their best interest to do so. The cost of the donation itself, including any training provided, would vary greatly depending on the particulars of the donation. Due to a lack of data on the types of donations that entities would offer as a result of this rulemaking, CBP is unable to estimate the cost of these donations to the public. In addition to the cost of the donated product or training itself, donors would bear some paperwork related costs with this rule. Under this rule, if finalized, entities must submit an offer of a donation in writing to CBP and provide all pertinent details regarding the scope, purpose, expected benefits, intended use, estimated costs, and proposed conditions of the donation. Based on discussions with CBP’s Office of Field Operations, CBP estimates that approximately 50 entities would make donations annually and that there would be one donation made per entity annually, for a total of 50 donations per year. CBP estimates that it would take an entity approximately 2 hours to write the offer of donation. In most cases, CBP believes that attorneys either employed or hired by the donor would write the offer of donation. Considering the median hourly wage of an attorney of \$80.83,^{2,3} writing the

² Source of median wage rate: U.S. Bureau of Labor Statistics, Occupational Employment Statistics, “May 2014 National Occupational Employment and Wage Estimates, United States—Median Hourly Wage by Occupation Code: 23–1011.” Updated March 25, 2015. Available at <http://www.bls.gov/oes/2014/may/oes231011.htm>. Accessed June 15, 2015. CBP adjusted this figure, which was in 2014 U.S. dollars, to 2015 U.S. dollars by applying a 1.0 percent annual growth rate to the figure, as recommended by the U.S. Department of Transportation’s value of travel time guidance. Source: U.S. Department of Transportation, Office of Transportation Policy. *The Value of Travel Time Savings: Departmental Guidance for Conducting*

offers of donation would result in a total annual time cost to donors of \$8,083 ($\$80.83 * 2 \text{ hours} * 50 \text{ written donation proposals}$). This would equate to a cost of \$161.66 per entity. CBP again notes that this is a voluntary program, and entities would only provide donations if the benefits of doing so outweigh the costs.

In addition to donor costs, this rule would introduce a time cost to CBP to process each offer of donation. As with donor costs, CBP's cost to receive and learn about the donated article would depend on the particulars of the donation. Also, accepting the donation is voluntary on CBP's part and the agency would only accept the donation if it is in CBP's best interest to do so. In addition to CBP's costs associated with receiving and learning about the donated article, there are quantifiable costs to CBP related to evaluating the donation and making a decision on whether to accept it under the conditions provided. CBP estimates, at a minimum, the agency's evaluation time to be approximately 10 hours for each of the 50 donations made to CBP annually. CBP predicts that in most cases, each written offer of donation would be evaluated by five CBP employees. Based on the average hourly wage for a general CBP employee of \$55.91,⁴ evaluating the 50 offers of donation each year would result in an annual time cost to CBP of \$139,775.00 ($\$55.91 * 5 \text{ CBP employees} * 10 \text{ hours} * 50 \text{ written donation proposals}$). On

Economic Evaluations Revision 2 (2015 Update), "Table 4 (Revision 2-corrected): Recommended Hourly Values of Travel Time Savings." April 29, 2015. <http://www.transportation.gov/sites/dot.gov/files/docs/Revised%20Departmental%20Guidance%20on%20Valuation%20of%20Travel%20Time%20in%20Economic%20Analysis.pdf>. Accessed June 1, 2016.

³ The total compensation to wages and salaries ratio is equal to the calculated average of the 2014 quarterly estimates (shown under Mar., June, Sep., Dec.) of the total compensation cost per hour worked for Professional and Related occupations (49.69) divided by the calculated average of the 2014 quarterly estimates (shown under Mar., June, Sep., Dec.) of wages and salaries cost per hour worked for the same occupation category (34.315). Source of total compensation to wages and salaries ratio data: U.S. Bureau of Labor Statistics. Employer Costs for Employee Compensation. *Employer Costs for Employee Compensation Historical Listing March 2004–December 2015*, "Table 3. Civilian workers, by occupational group: employer costs per hours worked for employee compensation and costs as a percentage of total compensation, 2004–2015 by Respondent Type: Professional and related occupations." June 10, 2015. Available at <http://www.bls.gov/ncs/ect/sp/ceccqrtn.pdf>. Accessed June 15, 2015.

⁴ CBP bases this wage on the FY 2015 salary and benefits of the national average of general, non-CBP Officer/frontline CBP positions, which is equal to a GS–12, Step 5. Source: Email correspondence with CBP's Office of Administration on June 25, 2015.

average, each offer of donation would cost CBP \$2,795.50 in evaluation time costs.

In summary, this rule could result in a total quantifiable annual cost to the public of \$8,083 and a total annual cost to CBP of \$139,775.00. Additionally, the public would bear a cost equal to the value of the donation and CBP would bear a cost to accept the donation. As these costs would vary depending on the particulars of the donation, CBP is unable to quantify them in this analysis. Because donations are voluntary for both the donor and CBP, donations would presumably only occur if the benefits to each party outweigh the costs.

Along with costs, the proposed rule would provide benefits to the donor and CBP. In particular, the proposed rule would enhance CBP's IPR enforcement capabilities by making donations of authentication devices, equipment, and training available to CBP personnel. This would help protect the entities making donations from the illegal importation of IPR-infringing products. The value of this benefit would vary depending on how much an entity believes IPR enforcement would improve because of its donation. As stated earlier, an entity would only make the donation if it believes the benefits of improved IPR enforcement outweigh the costs.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

This proposed rule, if finalized, would allow entities to voluntarily donate technology, training, and other support services to improve CBP's ability to enforce IPR potentially related to their goods. As any entity with intellectual property could make these donations, this rule may affect a substantial number of small entities. However, this rule imposes no new obligations on entities, including those considered small. Any small entity that chooses to make these donations would presumably do so because it believes the benefits of donating exceed the costs. Therefore, this rule would not have a significant economic impact on small

entities. Given these reasons, CBP certifies that this rule, if finalized, will not have a significant economic impact on a substantial number of small entities. CBP invites public comments on this determination.

Paperwork Reduction Act

An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

OMB approved collection 1651–0123 will be amended to reflect a new information collection proposed by this rule for written offers of donations to CBP of technology, training, and other support services in accordance with 19 CFR 133.61(b). CBP estimates that this rule would result in 50 responses each year and 100 burden hours to respondents annually. The new information collection would reflect the burden hours for each written offer of donation provided to CBP as follows:

Estimated number of annual respondents: 50.

Estimated number of annual responses: 50.

Estimated time burden per response: 2 hours.

Estimated total annual time burden: 100 hours.

Signing Authority

This proposed regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his delegate) to approve regulations related to certain customs revenue functions.

List of Subjects

19 CFR Part 133

Circumvention devices, Copying or simulating trademarks, Copyrights, Counterfeit goods, Customs duties and inspection, Detentions, Donations, Reporting and recordkeeping requirements, Restricted merchandise, Seizures and forfeitures, Technology, Trademarks, Trade names, Support services.

Proposed Amendments to Part 133 of the CBP Regulations

For the reasons set forth in the preamble, CBP proposes to amend 19 CFR part 133 as set forth below:

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

■ 1. The general authority citation for part 133 continues, and the specific authority for new subpart H is added, to read as follows:

Authority: 15 U.S.C. 1124, 1125, 1127; 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1202, 1499, 1526, 1624; 31 U.S.C. 9701.

* * * * *

Section 133.61 also issued under Sec. 308(d), Pub. L. 114–125; Sec. 507, Pub. L. 108–90; Sec. 2, Pub. L. 114–279.

Subpart G—[Reserved].

- 2. Add and reserve subpart G.
- 3. Add subpart H, consisting of § 133.61, to read as follows:

Subpart H—Donations of Intellectual Property Rights Technology and Support Services.

§ 133.61 Donations of intellectual property rights technology and support services.

(a) *Scope.* The Commissioner of U.S. Customs and Border Protection (CBP) is authorized to accept donations of hardware, software, equipment, and similar technologies, as well as donated support services and training, from private sector entities, for the purpose of assisting CBP in enforcing intellectual property rights. Such acceptance must be consistent with the conditions set forth in this section and section 308(d) of the Trade Facilitation and Trade Enforcement Act of 2015, as well as either section 482 of the Homeland Security Act of 2002 or section 507 of the DHS Appropriations Act of 2004.

(b) *Donation offer.* A donation offer must be submitted to CBP either via email, to IPRdonations@cbp.dhs.gov, or mailed to the attention of the Executive Assistant Commissioner, Office of Field Operations, or his/her designee. The donation offer must describe the proposed donation in sufficient detail to enable CBP to determine its compatibility with existing CBP technologies, networks, and facilities (e.g. operating system or similar requirements, power supply requirements, item size and weight, etc.). The donation offer must also include information pertaining to the donation's scope, purpose, expected benefits, intended use, costs, and attached conditions, as applicable, that is sufficient to enable CBP to evaluate the donation and make a determination as to whether to accept it. CBP will notify the donor, in writing, if additional information is requested or if CBP has determined that it will not accept the donation.

(c) *Agreement to accept donation.* If CBP accepts a donation of hardware, software, equipment, technologies, or to accept training and other support services, for the purpose of enforcing intellectual property rights, CBP will enter into a signed, written agreement with an authorized representative of the

donor. The agreement must contain all applicable terms and conditions of the donation. An agreement to accept training and other support services must provide that the services or training are offered without the expectation of payment, and that the service provider expressly waives any future claims against the government.

R. Gil Kerlikowske,
Commissioner.

Approved: January 09, 2017.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 2017–00653 Filed 1–13–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2008–D–0096 (Formerly Docket No. 2007D–0494)]

Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a revised draft guidance for industry entitled “Control of *Listeria monocytogenes* in Ready-To-Eat Foods.” The revised draft guidance is intended for any person who is subject to our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” and who manufactures, processes, packs, or holds ready-to-eat (RTE) foods. The revised draft guidance is intended to help such persons comply with the requirements of that regulation with respect to measures that can significantly minimize or prevent the contamination of RTE food with *L. monocytogenes* whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *L. monocytogenes*) that would significantly minimize *L. monocytogenes*.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we issue the final version of the

guidance, submit either electronic or written comments on the draft guidance by July 26, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2008–D–0096 for “Control of *Listeria monocytogenes* in Ready-To-Eat Foods.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be